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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/857,303

Applicant(s)

CHODOROWSKI ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-98 is/are pending in the application.
- 4a) Of the above claim(s) 44-58 and 86-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-43, 59-85, and 89-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This is a 371 of PCT/FR00/02687, filed September 28, 2000. The application also claims the benefits of foreign priority of France Application FR 99/1231, filed October 1, 1999.

### ***Election/Restrictions***

Applicant's election with traverse of the invention of Group I, claims 39-98, and specie of UVA sunscreen agents in Paper No. 9 is acknowledged. The traversal is on the ground(s) that each invention group are employing compounds with similar structure of metallo-organic groups. This is not found persuasive because the metallo-organic compounds herein claimed are considered structurally diverse. Some of the compounds are having X as moieties, wherein X can be practically any things since it can be a dermatological or cosmetic active. There is no limit as to what dermatological or cosmetic active can be. Therefore, they represents a vast arrays of compounds with various structures, for example, vitamin E and retinoic acid are dermatological active, which are encompassed by the term "dermatological or cosmetic active", and yet they are structurally different compounds. Moreover, some of the compounds contain substituents R, R', or R'' which can be structurally diverse. Because of the structural diversity among the recited metallo-organic compounds, they do not relate to a single inventive concept and the special technical features are not present.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-98 are pending.

Claims 44-58 and 86-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 39-43, 59-85, and 89-98 have been examined herein to the extent they read on the elected invention and species.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-43, 59-85, and 89-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the functionalized organic polymer or functionalized silicone polymer recited in the claims, does not reasonably provide enablement for the precursor of the functionalized organic polymer or functionalized silicone polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue

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experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claims are very broad. The term "precursor" encompasses any compounds that can be potentially reacted with another "precursor" in result of a functionalized organic or silicone polymer. Applicant fails to set forth the criteria that define neither a "precursor for functionalized organic polymer, nor precursor for functionalized silicone polymer". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "precursor" compound examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "precursor for functionalized organic polymer, nor precursor for functionalized silicone polymer", necessitating an exhaustive search for

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the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 39-43, 59-62, 65-85, 89, 90, and 93-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for UV-A sunscreen agents recited in claims 63, 64, 91, and 92, does not reasonably provide enablement for the derivatives of various UV-A sunscreen agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Attention is directed to the *In re Wands supra*, citing the eight factors as discussed above.

In the instant case, Applicant fails to set forth the criteria that define a "the derivatives of various UV-A sunscreen agents". It is not clear what would be considered as the derivatives of the UV-A sunscreen agent. There are no chemical or physical properties defined in the specification. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of " the derivatives of various UV-A sunscreen agents " examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "the derivatives of various UV-A sunscreen agents", necessitating an exhaustive search for the embodiments suitable to practice the claimed

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invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-43, 59-85, and 89-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term " at least partial hydrolysis " in claims 39 and 82 is a relative term which renders the claim indefinite. The term " at least partial hydrolysis " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what degree of hydrolysis would be considered as partial hydrolysis. Therefore, the metes and bounds of the claims cannot be ascertained.

The expression " the metal alkoxide and its condensation" recited in claim 39 renders the claim indefinite as to the condensation encompassed by the claims. It is not clear what would be condensed with the metal alkoxide compounds.

The terms "dibenzoylmethane derivatives", "camphor derivatives", benzimidazole derivatives", "benzoxazole derivatives", benzophenone derivatives", and "silane or polyorganosiloxane derivatives comprising benzophenone group(s)" recited in claims 62 and 90 render the claims indefinite as to the UV-A sunscreen compounds encompassed

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thereby. It is not clear what compound would be considered as the “derivatives” of these UV-A sunscreen agents.

The term “modified natural polymers” recited in claims 67 and 93 renders the claim indefinite as to the polymers encompassed by the claims. It is not clear what polymer would be considered as “modified natural polymer”.

The term “sol” in claim 82 renders the claim indefinite because the term is not understood.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-43, 59-85, and 89-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondet et al. (WO 98/44906, English equivalent US Patent 6,352,699 is also provided) in view of Yue et al. (US Patent 5,700,451).



Mondet et al. teaches a sol/gel composition comprising an organometallic compound, a functionalized organic or silicone polymer, a sufficient amount of water from hydrolysing the organometallic compound, and an alcohol (See the abstract). Mondet et al. teaches the organometallic compound as the compounds of Ia in the instant invention (See col. 3, line 26). Mondet et al. teaches the preferred organometallic compound as tetrapropyl zirconate (See col. 4, line 55). Mondet et al. teaches the preferred functionalized organic or silicone polymer as polydimethylsiloxane-diols (See col. 6, line 13). Mondet et al. teaches the preferred alcohol as ethanol (See col. 6, line 25). Mondet et al. also teaches that the composition can contain active cosmetic or dermatological agent such as sunscreen agent (See particularly col. 6, line 62 to col. 7, line 1). Mondet et al. also teaches weight ratio of the functionalized polymer to the organometallic compounds as 1:9 to 9:1 or 2:8 to 8:2 (See col. 6, lines 28-29). Mondet et al. also teaches the weight percent of the sol/gel composition in a cosmetic composition for skin (anti-wrinkle) as 10-70% (See col. 6, line 44-47).

Mondet et al. does not expressly teach a composition comprising the composition of Mondet et al. with an UV-A agent. Mondet et al. does not expressly teach the herein recited UV-A sunscreen agents be incorporated into the composition of Mondet et al. Mondet et al. does not expressly teach the herein claimed particle size of the composition, weight percent in the materials and the weight percent of the functionalized polymer.

Yue et al. teaches composition containing titanium alkoxide (an organometallic compound) is useful as sunscreen agent when hydrolyzed in the presence of water

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(See col. 4, line 1-3). Yue et al. teaches a second sunscreen agent can be added to the composition and the preferred sunscreen agent as 4,4'-*t*-butylmethoxydibenzoylmethane (See col. 9, line 57). Yue et al. teaches the titanium alkoxide particles is in the size of 50 to 150nm (see col. 4, line 27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an UV-A agent, such as the herein preferred UV-A sunscreen agent: 4,4'-*t*-butylmethoxydibenzoylmethane, into the composition of Mondet et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the herein claimed particle size of the composition, weight percent in the materials and the weight percent of the functionalized polymer.

One of ordinary skill in the art would have been motivated to incorporate an UV-A agent, such as the herein preferred UV-A sunscreen agent: 4,4'-*t*-butylmethoxydibenzoylmethane, into the composition of Mondet et al. It is known that UV-A sunscreen agent can be incorporated into the composition of Mondet et al. Therefore, incorporating any UV-A sunscreen agent, such as 4,4'-*t*-butylmethoxydibenzoylmethane, would be reasonably expected to be useful. In addition, Yue et al. further provides a motivation to combine the titanium alkoxide containing composition with 4,4'-*t*-butylmethoxydibenzoylmethane since 4,4'-*t*-butylmethoxydibenzoylmethane is the preferred UV-A sunscreen agent. Combining titanium alkoxide with the preferred UV-A sunscreen agent, such as 4,4'-*t*-butylmethoxydibenzoylmethane, would be reasonably expected to be useful as sunscreen composition.

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One of ordinary skill in the art would have been motivated to adjust the herein claimed particle size of the composition, weight percent in the materials and the weight percent of the functionalized polymer because the optimization of result effect parameters (e.g., weight ratio of the actives, particle size, weight amount of the polymers) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui  
Patent Examiner  
Art Unit 1617  
July 13, 2003